

## **X. CONCLUSION**

Through this petition, OSMA requests the reclassification of metal/polymer constrained hip replacements from class III into class II. In support of this request, clinical literature on constrained hip arthroplasty has been provided. In addition, the constrained hip has a long history of commercial distribution that has defined the risks and potential adverse effects associated with this device. We believe this petition shows that these risks can be adequately controlled through FDA's established authority over class II devices.